A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL

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DECLARATION BY THE CANDITATE

TITLE OF DISSERTATION	A comparative evaluation of clinical efficacy and patient comfort in surgical scrapping and diode laser technique for gingival depigmentation: A clinical trial
PLACE OF STUDY	K.S.R. Institute of Dental Science and Research
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NAME OF THE GUIDE	Dr. N. Raghavendra Reddy
HEAD OF THE DEPARTMENT	Dr. N. Raghavendra Reddy

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Date:

Place:

Signature of the Guide

Dr. N.RAGHAVENDRA REDDY., M.D.S

PROFESSOR & H.O.D.

K.S.R. INSTITUTE OF DENTAL SCIENCE AND RESEARCH

TIRUCHENGODE

ENDORSEMENT BY THE H.O.D, PRINCIPAL/ HEAD OF THE INSTITUTION

This is to certify that Dr. M. RAGUL, Post Graduate student (2012-2015) in the Department of Periodontics, K.S.R. Institute of Dental Science and Research, has done this dissertation titled "**A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL**" under our guidance and supervision in partial fulfillment of the regulations laid down by the **Tamilnadu Dr.M.G.R. Medical University**, Chennai for **M.D.S., (**Branch – II) **Periodontics** degree examination.

Seal & signature of H.O.D.

Dr. N.RAGHAVENDRA REDDY., M.D.S.

PROFESSOR AND GUIDE

Seal & signature of Principal

Dr. G.S.KUMAR., M.D.S.

PRINCIPAL

K.S.R. INSTITUTE OF DENTAL SCIENCE AND RESEARCH

TIRUCHENGODE

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LIST OF ABBREVATIONS

1	TYR	Tyrosinase
2	TYRP1	Tyrosinase-related protein 1
3	DCT	Dopa chrome tautomerase
4	DOPA	Dihydroxyphenylalanine
5	DHI	Dihydroxy indole
6	ADMA	Acellular dermal matrix allograft
7	GaAlAs	Gallium aluminum arsenide
8	LLLT	Low level laser therapy
9	InGaAsP	Indium gallium arsenide phosphorus
10	InGaAs	Indium gallium arsenide
11	KTP	Potassium titanyl phosphate
12	ArF	Argon fluoride
13	XeCl	Xenon chloride
14	HeNe	Helium neon
15	Nd:YAG	Neodymium yttrium aluminum and garnet
16	Er:YAG	Erbium-doped: yttrium, aluminum, and garnet

Introduction

INTRODUCTION

Esthetics has become a significant concern in modern society, [1] which aims at merging both the appearance and beauty in conjunction with function and individual needs of every patient. [2] A pleasing smile expresses warmth, calmness, a feeling of joy, success, sensuality, affection, and courtesy, and can reflect self-confidence and kindness. An esthetically pleasing smile is not only dependent on components such as tooth position, size and shape, but also on the gingival color, the amount of gingival display and the framing of the lips. All of these components should form a harmonic and symmetric entity to contribute for a much attractive smile. [3]

Gingival color plays an important role in achieving overall esthetics. [1] It depends primarily upon the number and size of the blood vessels, thickness of epithelium, degree of keratinization and pigments within the gingival epithelium. Melanin, carotene, reduced hemoglobin and oxyhemoglobin are the prime pigments contributing to the normal color of the oral mucosa. [4]

Melanin is the most common endogenous, nonhemoglobin-derived brown pigment produced by melanocytes present in the basal layer of the epithelium. Excessive deposition of melanin located in the basal and suprabasal cell layers of the epithelium causes gingival hyperpigmentation.[5] Gingival pigmentation was noticed as highest being in the attached gingiva and interdental papilla (25.4%) and least being in the marginal gingiva and interdental papilla (10.2%). [6]

Gingival depigmentation is a periodontal plastic surgical procedure where the gingival hyperpigmentation is removed or reduced by different techniques [5] which

includes De-epithelization (Scalpel, and Gingival abrasion technique using diamond bur), Gingivectomy, Gingivectomy with free gingival autografting, Acellular dermal matrix allograft, Electrosurgery, Cryosurgery, Chemical agents, and Lasers. [4]

Scalpel de-epithelization is simple and effective, and most economical as compared to other techniques, which require more advanced armamentarium. The healing by scalpel & blade technique is faster than with diode laser. However, it can cause rapid and more hemorrhage during or after surgery. [4]

In dentistry, lasers have been used since the beginning of the 1980s. Semiconductor diode laser has been used for gingivectomy, frenectomy, operculectomy, incisional and excisional biopsy, soft tissue tuberosity reduction, coagulation of graft donor site, and exposure of soft tissue covering osseointegrated implants. [3] The advantages of diode laser are easy handling, short treatment line, hemostasis, sterilization effects and excellent coagulation. [4]

The present study is undertaken to compare the clinical efficacy and patient comfort of surgical scrapping and diode laser technique used for gingival depigmentation. An attempt has been made to assess gingival color change, patient comfort and also correlate the clinical parameters at baseline, first day, 1week, 1month, 3 months, and 6 months interval by using Dummet oral pigmentation index, Hedin melanin index, Bleeding, Visual analog scale and Photographs.

Aims & Objectives

AIMS AND OBJECTIVES

1. To evaluate and compare the intensity of pigmentation (Dummet oral pigmentation index) and the extent of pigmentation (Hedin melanin index) at baseline, 1 month, 3 months and 6 months by surgical scrapping and diode laser in the treatment of gingival hyperpigmentation.
2. To estimate and compare the amount of bleeding encountered immediately, 1 day, 1week, 1month and 3 months after the surgical scrapping and diode laser in the management of gingival hyperpigmentation.
3. To evaluate and compare the pain in surgical scrapping and diode laser in the treatment of gingival hyperpigmentation by visual analog scale (VAS) at 1 day and 1 week after the procedure.
4. To assess the colour change by taking photographs at baseline, 1month, 3 months and 6 months after the treatment.

Review of Literature

REVIEW OF LITERATURE

MELANOCYTE BIOLOGY:

MELANOGENESIS:

Melanin biosynthesis appears in highly specialized cells, called melanocytes, within membrane-bound organelles known as melanosomes. Melanosomes are transferred to surrounding keratinocytes through dendrites, where they play a major role in photoprotection. The anatomical link between keratinocytes and melanocytes is known as "the epidermal melanin unit". It is estimated that each melanocyte is in contact with approximately forty keratinocytes in the basal and suprabasal layers. [7]

For the proper synthesis and distribution of melanin, several important steps should take place, they are; [7, 8, 9]

1. The development and migration of melanoblasts from the neural crest to peripheral sites:

In the 2nd month of human intra embryonic life, the melanocyte precursor cells (melanoblasts), derive from the neural crest and migrate all over the mesenchyme of the developing embryo. They reach precise target sites, mainly the dermis, epidermis, and hair follicles, the uveal tract of the eye, the stria vasculare, the vestibular organ and the endolymphatic sac of the ear, and leptomeninges of the brain. This migration process takes place between the tenth and twelfth week of development for the dermis and approximately two week later for the epidermis in humans. The neural crest-derived cells survive and migrate during embryogenesis is highly reliant on interactions between precise receptors on the cell surface and their extracellular ligands.

2. Differentiation of melanoblasts into melanocytes:

After reaching their final destinations, melanoblasts differentiate into melanocytes, which are already established at epidermal-dermal junction sites at about the sixth month of fetal life.

3. Survival and proliferation of melanocytes:

Melanocytes are established within fetal epidermis as early as fifty days of gestation. Dermal melanocytes are reduced in the gestation period and virtually disappear by birth, whereas epidermal melanocytes recognized at the epidermal-dermal junction continue to proliferate and commence to produce melanin.

4. Formation of melanosomes and production of melanins:

Once established *in situ*, melanocytes begin producing melanosomes, these melanosomes are well organized elliptic membrane bound organelles in which melanin synthesis takes place. They are detected by using electron microscopy during the fourth month of gestation. Melanosomes are divided into four maturation stages (I–IV) based on the structure and the quantity, quality, and arrangement of the melanin produced (fig 1 & 2).

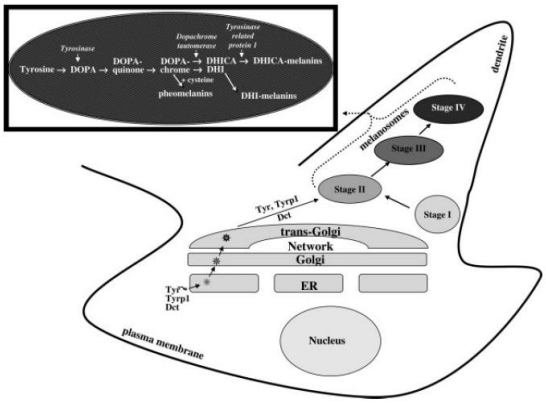


Figure 1: Schematic of a melanocyte: the engine for melanin production

Nascent melanosomes are gathered in the perinuclear region near to the Golgi stacks, receiving all enzymatic and structural proteins necessary for melanogenesis. Stage I melanosomes are spherical vacuoles deficient tyrosinase (TYR) activity and it has no internal structural components. However, tyrosinase can be detected in the Golgi vesicles, and it has been exposed that it is consequently trafficked to stage II melanosomes. At this time, the elongated, fibrillar organelles known as stage II melanosomes are formed from stage I melanosomes in the presence and correct processing of Pmel17, which is most essential melanosomal structural protein. The stage II melanosomes have tyrosinase and show minimal deposition of melanin. After this, melanin synthesis begins and the pigments are uniformly deposited on the internal fibrils, at this time they are termed as stage III melanosomes.

Melanosom features	Stage I	Stage II	Stage III	Stage IV
				
Shape	Spherical	Elongated	Elliptical, ellipsoidal	Elliptical, ellipsoidal
Internal structure	–	Matrix fibrils are visible	Matrix fibrils are visible	Matrix fibrils are covered by polymerized melanin
TYR	–	+	+	+
TYRP1	–	+	+	+
TYRP2	–	+	+	+
Melanin synthesis	–	–	Begins, settle on internal fibrils	Filled by melanin
Color			Brown	Dark brown to black

Figure 2: Developmental stages of melanosomes during melanin synthesis.

Their final developmental stage (IV) takes place in highly pigmented melanocytes; these melanosomes are either elliptical or ellipsoidal, electron-opaque due to complete melanization, and have reduced TYR activity. The developmental stages refer most importantly to eu-melanosomes (having black-brown pigments); however, they are somewhat similar to pheo-melanosomes (having yellow-reddish melanin), the only difference is that the latter remain round and are not fibrillar for the period of maturation.

As a minimum three enzymes are necessary to synthesize different types of melanin from melanosomes. The most important enzyme is tyrosinase, which is responsible for the essential steps of melanogenesis (the rate-limiting initial step of tyrosine hydroxylation), and tyrosinase-related protein 1 (TYRP1) and DOPAchrome tautomerase (DCT) are further involved in altering the melanin into different types. In addition to these, melanosomes comprise other melanocyte-specific proteins and it has structural functions (*e.g.*, Pmel17) or P protein- or membrane-associated transporter protein (MATP) regulating the pH within melanosomes, or that play as up till now unclear roles, such as the melanoma antigen recognized by T cells or oculo cutaneous albinism-1 protein.

Tyrosinase enzyme (monophenol, 3,4-β-dihydroxyphenylalanine oxygen oxidoreductase) is a single chain type I membrane glycoprotein and it catalyzes the hydroxylation of tyrosine to β-3,4-dihydroxyphenylalanine (DOPA) (which is the early rate-limiting step in melanogenesis) and the following oxidation of DOPA to DOPAquinone. A number of structural similarities are shared by TYR, TYRP1, and DCT and follow similar biosynthetic, processing, and trafficking pathways. Chaperones assist

their maturation, and calnexin regulating the correct folding of tyrosinase. DOPA and its derivatives undergo further metabolism by other melanocyte-specific enzymes, including TYRP1 and DCT, results in the synthesis of a black brown pigment called eumelanin (Fig 3). DOPAquinone generate 5,6-dihydroxy indole (DHI) melanins after several steps of decarboxylation, oxidation, and polymerization. In the presence of DCT, the carboxylic acid group is retained in 5,6-dihydroxyindole-2-carboxylic acid (DHICA) when derived from DOPAchrome, and therefore the so-called DHICA melanins are produced. The formation of pheomelanin involves the synthesis of cysteinyl dopa conjugates from DOPAquinone following the production of DOPA from tyrosine. TYRP1 is essential for the accurate trafficking of tyrosinase to melanosomes, and DCT also appears to be involved in the detoxification processes occur within melanosomes.

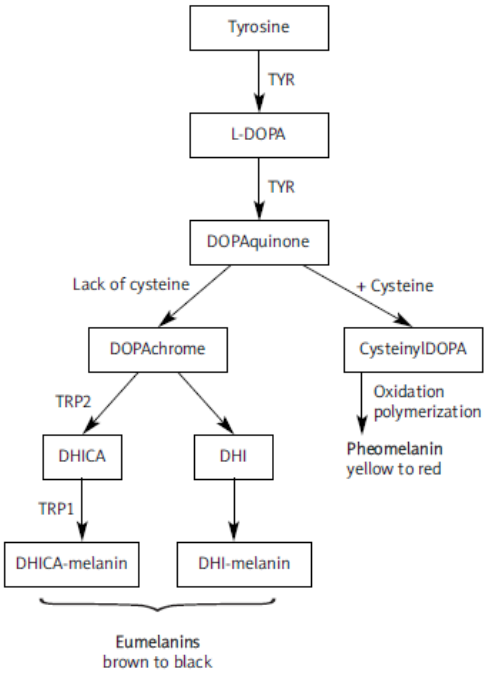


Figure 3: Simplified scheme of the melanin synthesis in melanocytes during melanogenesis.

Eumelanin, pheomelanin, mixed melanins (a combination of the two), and neuromelanin are type of melanins, which are polymorphous and multifunctional biopolymers. Two chemically different types of melanin pigments are produced by mammalian melanocytes, namely black brown eumelanin and yellow-reddish pheomelanin. Melanin pigments contain a common arrangement of repeating units connected by carbon-carbon bonds, and it differs from each other with respect to their chemical, structural, and physical properties.

Eumelanin is an extremely heterogeneous polymer and it has DHI and DHICA units in reduced or oxidized states. Pheomelanin contains primarily sulfur-containing benzothiazine derivatives. Both eumelanin and pheomelanin are involved in binding to cations, anions, drugs, and chemicals, *etc.*, because of their chemical structure and so it has a significant protective role within melanocytes.

Dopaminergic neurons of the human substantia nigra produces neuromelanin, and it can chelate with redox active metals (Cu, Mn, Cr) and toxic metals (Cd, Hg, Pb), and thus protects against their capability to promote neurodegeneration. [7, 8, 9]

TABLE 1: PROPOSED NEW CLASSIFICATION OF GINGIVAL PIGMENTATION: [10]

Class	Criteria of classification
I	Coral pink/salmon pink colored gingiva
	Localized/Isolated spots/areas of gingival melanin pigmentation

II	which does not involve all the three parts of gingiva, that is, attached, free, and papillary gingiva, Mild to moderate pigmentation Severe/intense pigmentation
III	Localized/Isolated unit/s of melanin pigmentation which involve all the three parts of gingiva, that is, attached, free, and papillary gingiva Mild to moderate pigmentation, Severe/intense pigmentation
IV	Generalized diffuse pigmentation which involve all the three parts of gingiva that is, attached, free, and papillary gingiva Mild to moderate pigmentation Severe/intense pigmentation
V	Tobacco associated pigmentation like smoker's melanosis and chewing tobacco
VI	Gingival pigmentation due to exogenous pigments: Amalgam tattoos, Cultural gingival tattooing, Drinks, Food colors, Habitual betelnut/khat chewing, Lead-Burtonian line, Mercury,Silver, Arsenic, Bismuth, Graphite, Otherf oreign bodies, Topical medications, Idiopathic.
VII	Gingival pigmentation due to endogenous pigments Bilirubin, Blood breakdown products: Ecchymosis, Petechiae, Hemochromatosis, Hemosiderin
	Drug-induced gingival pigmentation:

VIII	ACTH, Antimalarial drugs, Chemotherapeutic agent-busulfan and doxorubicin, Minocycline, Oral contraceptives, Phenothiazines
IX	Gingival pigmentation associated with systemic diseases and syndromes: Addison's disease, Albright's syndrome, Basilar melanosis with incontinence, Beta thalassemia, Healed muco-cutaneous lesions-Lichen planus, Pemphigus, Pemphigoid, Hereditary hemorrhagic telangiectasia, HIV-associated melanosis, Neurofi bromatosis, Peutz-Jeghers and other familial hamartoma syndromes, Pyogenic granuloma/Granulomatous epulis
X	Pigmented benign and malignant lesions involving the gingival: Angiosarcoma, Hemangioma, Kaposi's sarcoma, Malignant melanoma, Melanocytic nevus, Pigmented macule.

TABLE 2: PROPOSED GINGIVAL MELANIN PIGMENTATION AND PIGMENTED LESIONS INDEX: [10]

Score	Criteria of classification
Score 0	Coral pink-colored gingiva, no gingival pigmentation, and/or pigmented lesions
Score 1	Mild, solitary/diffuse, gingival melanin pigmentation involving anterior gingiva, with or without the involvement of posterior gingiva

Score 2	Moderate to severe, solitary or diffuse, gingival melanin pigmentation involving anterior gingiva with or without the involvement of posterior gingiva
Score 3	Gingival melanin pigmentation only in posterior gingiva
Score 4	Tobacco-associated pigmentation: Smoker's melanosis, chewing tobacco
Score 5	Gingival pigmentation due to exogenous pigments-Amalgam tattoos arsenic, bismuth, chewing betel nut, cultural gingival tattooing, drinks, food colors, lead-burtonian line, mercury, silver, topical medications, idiopathic etc
Score 6	Gingival pigmentation due to other endogenous pigments: Bilirubin, blood breakdown products, ecchymosis, hemochromatosis, hemosiderin, petechiae etc
Score 7	Drug-associated gingival pigmentation: Antimalarial drugs, minocycline, oral contraceptives etc
Score 8	Gingival pigmentation associated with other causes: Addison's disease, albright's syndrome, basilar melanosis with incontinence, hereditary hemorrhagic telangiectasia, HIV patients, lichen planus, neurofi bromatosis, Peutz-Jeghers syndrome, etc
Score 9	Pigmented benign lesions: Hemangioma, melanocytic nevus, pigmented macule
Score 10	Pigmented malignant lesions: Angiosarcoma, Kaposi's sarcoma, malignant melanoma

PHYSIOLOGIC AND/OR PATHOLOGIC FACTORS FOR GINGIVAL HYPERPIGMENTATION: [11]

Physiologic Oral Pigmentation (Melanin is normally produced by melanocytes)

Pathologic Oral Pigmentation:

1. Endogenous Factors: Diseases that increase melanin pigmentation (Addison's disease, Peutz-Jeghers syndrome, Albright syndrome (polyostotic fibrous dysplasia) and von Reckling Neurofibromatosis), Bile pigments can stain skin and mucous membranes, the deposition of iron in hemochromatosis can stain oral mucous membranes.
2. Exogenous Factors: Atmospheric irritants (coal and metal dust), Coloring agents in food or lozenges, Tobacco, Amalgam tattoo, Metallic pigmentation (bismuth, arsenic, mercury, lead, and silver), Antimalarial drugs.

Dummet CO et al (1945) [12] investigated the clinical appearance of pigment variation in oral tissues of Negroes and he found that pigmentation in the labial side was more than that of the lingual side as well as it was more in the anterior region than in the posterior. Although it is assumed that gingival pigmentation is genetically determined, Dummett has suggested that environmental factors play a role in its degree. Observations made from this study showed that the lingual & posterior parts were less exposed to variations in temperature, dust particles & other irritating factors and therefore had lower degrees of pigmentation and racial determinants.

Dummet CO et al (1964) [13] proposed the Dummett-Gupta Oral Pigmentation Index (DOPI Assessement) as an epidemiological tool to obtain the comparative estimates on the occurrence of oral pigmentation. The index represents the assignment of a numerical value to the total melanin pigmentation seen upon clinical examinations of various oral tissues. In a pilot study conducted on 401 Negroes, DOPI Assessments was higher in females, increased with darkening of complexion and commonly higher in the maxilla.

Hedin CA et al (1977) [14] examined the frequency and extension of the melanin pigmentation in the attached gingiva and its relation to tobacco smoking. All of the patients with pigmentation proved to be tobacco smokers. The pigmentation was given the name "smokers' melanosis". Between 12.9% and 14.9% of those examined and between 25.5% and 31.0% of those who smoked had smokers melanosis. Patients with smokers' melanosis had significantly higher tobacco consumption than smokers without pigmentation. In 95.2%, smokers' melanosis was found in the mandible and was most common in the attached gingiva on the labial side of the canines and incisors.

Patsakas A et al (1981) [15] carried out a study to determine the distribution of melanin granules in different anatomical areas of the gingiva and to relate the density of melanin granules to the degree of gingival inflammation and they concluded that melanophores of the gingival epithelium are mainly located in the attached rather than the free gingiva, and the number of melanophores and the density of the melanin granules decreases gradually starting from the free gingival groove area toward the gingival crest and toward the mucogingival junction. The number of melanophores of the gingival epithelium per unit area is directly correlated with the severity of inflammation (numbers

of inflammatory cells) in the subjacent connective tissue of the attached gingiva and the density of the melanin granules of the vestibular gingival epithelium is directly correlated with the melanin granule density of the subjacent connective tissue of both the free and attached gingiva.

Hedin CA et al (1991) [16] examined 234 and 233 patients in Thailand and Malaysia respectively concerning tobacco and chewing habits and the presence of oral melanin pigmentation. It was found that tobacco smokers had more significant pigmented oral surface than non tobacco users and they concluded that tobacco smoking stimulates oral melanocytes to a higher melanin production.

Takashi et al (2005) [17] studied the relationship between gingival pigmentation of children and passive smoking by a case-control study involving 59 nonsmoking children selected from patient records of a dental clinic in a rural town in Japan and they concluded that excessive pigmentation in the gingiva of children is associated with passive smoking.

La Porta et al (2005) [18] reported a 45 years old, Caucasian female presenting with pigmentation of the gingiva, lips and nail bed. Past medical history revealed initiation of minocycline therapy 6 months earlier. Histopathologic examination of biopsy specimen of gingiva showed increased evidence of melanin/ melanocytes in the epithelium and melanin/ melanophages in the connective tissue and nine months after cessation of therapy the patient exhibited marked reduction in pigmentation.

Rawal S et al (2007) [19] examined four black females of West African origin, representing three different ethnic groups presenting with various chief complaints. All exhibited diffuse pigmentation of the maxillary vestibular gingiva extending to the

second premolar areas, without any associated radiographic abnormalities and one case was biopsied for histopathologic evaluation. Questioning revealed that the women had undergone one or more sessions of traditional gingival tattooing and the biopsy exhibited dense fibrous connective tissue containing aggregates of foreign material consistent with a foreign body tattoo and they concluded that gingival tattooing, a cultural practice prevalent in certain African ethnic groups, results in diffuse pigmentation. Outside of Africa, it may be misinterpreted as racial pigmentation or pose a diagnostic puzzle.

MANAGEMENT:

To treat depigmentation and to enhance esthetics, numerous techniques have been employed from time to time.

Various techniques;

De-epithelization (Scalpel technique, Gingival abrasion technique using diamond bur and Combination of the scalpel and bur), Gingivectomy, Gingivectomy with free gingival autografting, Acellular dermal matrix allograft (ADMA), Electrosurgery, Cryosurgery (Using liquid nitrogren and Using a gas expansion system), Chemical agents (90% phenol and 95% alcohol and Ascorbic acid), Laser (Nd:YAG, Semiconductor diode laser, CO2 laser, Argon laser). [4]

SCALPEL TECHNIQUE:

Bhusari et al (2011) [20] studied the comparison between the scalpel technique and electrosurgery for depigmentation by split mouth design and they concluded that scalpel

surgical technique, which is simple, easy to perform, cost effective, and minimum discomfort to the patient had esthetically pleasing results than electrosurgery.

Bhatsange et al (2011) [21] compared the scalpel technique and electrosurgery. depigmentation was carried out by scalpel technique in maxillary gingiva and mandibular gingiva by electrosurgical method and they concluded that scalpel technique offers advantage of being easy, effective, less discomfort with esthetically acceptable results in comparison with electrosurgical method.

Shah S et al (2012) [22] investigated a total of 48 patients (27 male, 21 female) with a chief complaint of black gums and it was treated by surgical depigmentation procedure. The results obtained in all the patients were minimum discomfort and maximum patient satisfaction, with no signs of recurrence after a 30‐month follow‐up period.

Kasagani et al (2012) [23] reported three cases of gingival hyperpigmentation, managed by three different techniques: electrosurgery; scalpel surgery; and surgical abrasion and they found that small areas of repigmentation were seen in the areas treated by electrosurgery and no evidence of repigmentation in the areas treated by scalpel surgery; and surgical abrasion.

Lawande S et al (2012) [24] carried out a combination of scalpel and abrasion technique for depigmentation and results revealed that no sign of gingival repigmentation at the end of 6 months and patient expressed great satisfaction. They concluded that scalpel and abrasion technique was simple, economical and clinically effective.

Thangavelu et al (2012) [2] presented a case series describing three simple and effective surgical depigmentation techniques - scalpel, electrosurgery, and diode lasers

and they concluded that use of diode laser was simple, effective, yielded good results along with good patient satisfaction.

Hegde et al (2013) [25] studied to compare the surgical stripping; carbon dioxide (CO_2); and erbium-doped:yttrium, aluminum, and garnet (Er:YAG) laser techniques for gingival depigmentation and to evaluate their effect on histologic changes in melanocyte activity and clinical repigmentation and they found that repigmentation was least after the surgical stripping procedure, and clinical repigmentation after gingival depigmentation is an outcome of histologic changes in the melanocyte activity and density of the melanin pigments. They concluded that the surgical stripping procedure remains the gold standard for gingival depigmentation and the Er:YAG and the CO2 lasers can be used as effective, newer alternatives for esthetic gingival depigmentation but with distinct limitations and differences.

Antony et al (2013) [26] reported two cases of gingival hyperpigmentation managed by surgical method and clinical follow up revealed that no complaints of post-operative pain or sensitivity. The gingiva appeared healthy and no repigmentation was observed. They concluded that the procedure adopted is quite simple, cost effective and less painful with minimal tissue loss and hence can be repeated without complication keeping in mind the fact that repigmentation is a possibility in most cases.

Abhinaya et al (2014) [27] carried out a scalpel surgical procedure in order to perform the depigmentation in upper and lower anterior gingiva and they found that certain localized areas of repigmentation were seen at the end of 1 month. At the end of 24 months, no further repigmentation was seen.

Bhuvaneswarri et al (2014) [28] presented case series using high speed rotary instrument, with NO.8 diamond bur and scalpel technique and results showed that wound healing was almost completed, but slight redness still remained at 4 weeks after surgery in bur abrasion areas and in scalpel treated areas wound healing was almost completed, at 4 weeks after surgery. They concluded that both the scalpel technique and the high speed rotary instrument seem to be effective in the esthetic treatment of gingival melanin hyper pigmentation.

LASER:

HISTORY:

Einstein in 1917 gave the first theoretical foundation of LASER and MASER using Plank's law of radiation that was based on probability coefficients (Einstein coefficients) for absorption and spontaneous and stimulated emission of electromagnetic radiation. Theodore Maiman was the first person to demonstrate the initial practical laser in 1960 after the reports by numerous scientists, including R.W. Ladenburg gave the first theoretical description on stimulated emission and negative absorption in 1928 and its experimental demonstration given by W.C. Lamb and R.C. Rutherford in 1947 and the proposal of Alfred Kastler on optical pumping in 1950 and its demonstration by Brossel, Kastler, and Winter two years later. Maiman's first laser was based on optical pumping of synthetic ruby crystal using a flash lamp that generated pulsed red laser radiation at 694 nm. Iranian scientists Javan and Bennett made the first gas laser using a mixture of He and Ne gases in the ratio of 1: 10 in the 1960. R. N. Hall demonstrated the first diode laser made of gallium arsenide (GaAs) in 1962, which emitted radiation at 850 nm, and

later in the same year Nick Holonyak developed the first semiconductor visible-light emitting laser. [29]

BASIC LASER SCIENCE:

The word LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. [30]

LIGHT:

Light is a form of electromagnetic energy that performs as a particle and a wave. Photon is the basic unit of this energy. Ordinary light and Laser light are significantly different. Ordinary light is usually a white diffused glow, and is the sum of the many colors of the visible spectrum-violet, blue, green, yellow, orange, and red and produced by a table lamp as example.

Laser has a property called monochromacity, light of one specific color. In dental applications that color may be visible or invisible, and the three additional characteristics are collimation, coherency, and efficiency. Collimation refers to the beam with specific spatial boundaries, insures that there is a constant size and shape of the beam which is emitted from the laser cavity. Coherency is the light waves produced in the instrument are all the same and are in phase with one another and identical wave shapes, all the peaks and valleys are equivalent. The efficiency is clinically useful feature of laser light.

The wave of photons produced by a laser and it is defined by three measurements. They are velocity, amplitude, and wavelength. Velocity is the speed of light. Amplitude is the total height of the wave oscillation from the top of the peak to the bottom on a vertical axis, the larger the amplitude, the greater the amount of useful work that can be

performed. The wavelength is the distance between any two corresponding points on the wave on the horizontal axis.

AMPLIFICATION:

Amplification is part of a process which occurs inside the laser. The production of laser light is better understood by identifying the components of a laser instrument produced.

At the center of the device there is an optical cavity. The core of the cavity is called the active medium comprised of chemical elements, molecules, or compounds. Lasers are generically named based on material of the active medium, which can be a solid-state semiconductor or container of gas, a crystal. Argon and CO2 are the two gaseous active medium lasers used in dentistry. The solid-state semiconductor wafers made with multiple layers of metals such as gallium, aluminum, arsenic and indium or solid rods of garnet crystal grown with various combinations of aluminum, yttrium, gallium, and scandium and then doped with the elements of neodymium, chromium, or erbium. There are two mirrors, placed parallel to each other, one at each end of the optical cavity. An excitation source Surrounds this core, either an electrical coil or a flash lamp strobe device, provides energy into the active medium. Focusing lenses, a cooling system, and other controls complete the mechanical components (Fig.4).

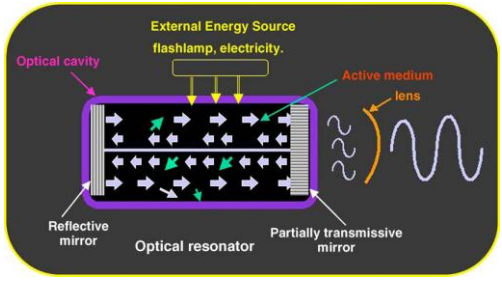


Figure 4: The basic components of a laser.

STIMULATED EMISSION:

In 1900 German physicist Max Planck introduced the term ‘‘stimulated emission’’ has its basis in the quantum theory of physics, and further conceptualized as relating to atomic architecture by a physicist from Denmark, Niels Bohr.

The smallest unit of energy, quantum is absorbed by the electrons of an atom or molecule, causing a brief excitation, then a quantum is released, called spontaneous emission. This quantum emission, also termed a photon, can be of various wavelengths because there are several electron orbits with different energy levels in an atom. Incandescent light is produced by this manner. The tungsten filament is energizes by electrical energy of a household lamp, causing it to glow.

Albert Einstein theorized the stimulated emission as an additional quantum of energy traveling in the field of the excited atom which has the same excitation energy level would result in a release of two quanta. It would occur just before the atom could undergo spontaneous emission. The energy is emitted, or radiated, as two identical photons, traveling as a coherent wave (Fig 5).

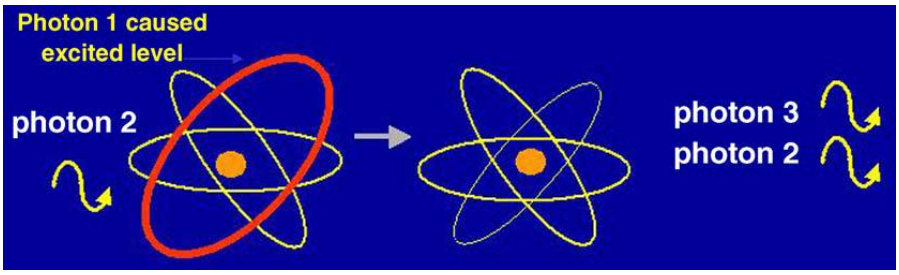


Figure 5: Stimulated emission.

These photons are able to energize more atoms, and emit additional identical photons, stimulating more surrounding atoms. A population inversion occurs, If the conditions are right, meaning that a majority of the atoms of the active medium are in the elevated state rather than the resting state. There must be a pumping mechanism, a constant supply of energy, to maintain this excitation. The amplification is produced by placing mirrors at each end of the active medium which reflect these photons back and forth to allow further stimulated emission, and successive passes through the active medium increase the power of the photon beam. The optical cavity must be cooled because some heat is generated during the process. The parallelism of the mirrors insures that the light is collimated. One of the mirrors is selectively transmissive, allowing light of sufficient energy to exit the optical cavity.

RADIATION:

Radiation: it is the light waves produced by the laser as a specific form of electromagnetic energy. The electromagnetic spectrum is the entire collection of wave energy ranging from gamma rays with wavelength about 10-12 m, to radio waves, whose wavelength can be thousands of meters. The ionizing waves have very short wavelengths, below approximately 300 nm. The term ionizing refers to the fact that higher-frequency (smaller wavelength) radiation has a large photon momentum, measured in electron volts per photon. This higher photon energy can penetrate deeply to the biologic tissue and produce charged atoms and molecules. Wavelengths larger than 300 nm have less photon energy and when it interacts with tissue cause excitation and heating of the tissue. All available dental laser devices have emission wavelengths of approximately 0.5 lm (or 500 nm) to 10.6 lm (or 10,600 nm). They are therefore within the visible or the invisible

infrared non ionizing portion of the electromagnetic spectrum and emit thermal radiation. The junction of ultraviolet and visible violet light is the dividing line between the ionizing (ie, the cellular DNA mutagenic portion of the spectrum) and the nonionizing portion (Fig 6). [31]

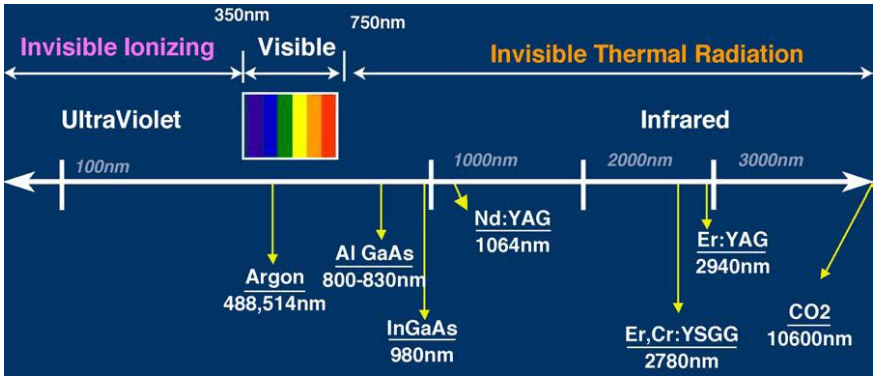


Figure 6: A portion of the electromagnetic spectrum showing dental laser wavelengths being used for treatment.

LASER DELIVERY SYSTEMS:

The existing range of laser delivery systems includes the following:

1. Articulated arms (with mirrors at joints) – for UV, visible, and infrared lasers
2. Hollow waveguides (flexible tube with reflecting internal surfaces) – for middle and far infrared lasers
3. Fiber optics – for visible and near infrared lasers. [32]

LASER EMISSION MODES:

The monochromatic (light of one specific wavelength), directional (low divergence), and coherent (all waves are in a certain phase relationship to each other) Laser lights can

be delivered onto target tissue as a continuous wave, gated-pulse mode, or free running pulse mode.

In continuous wave mode, the beam is emitted at one power level continuously as long as the foot switch is pressed. In gated-pulse mode, the laser is in an on and off mode at periods. The duration of the on and off timer is in micro seconds. In free running pulse mode, very large laser energy is emitted for an extremely short span in microseconds, followed by a relatively long time at which the laser is off.

LASER ENERGY AND TISSUE TEMPERATURE:

The photothermal effect (ie, the conversion of light energy into heat), the principal effect of laser energy on tissue depends on the degree of temperature rise and the corresponding reaction of the interstitial and intracellular water. This effect is mainly influenced by rate of temperature rise and is dependent on cooling of the surgical site and the ability of surrounding tissue's to dissipate the heat. The emission mode, power density, and time of exposure are the other important parameters used for this procedure. Heating occurs as the laser energy is absorbed.

The first event occurs when the tissue temperature is elevated above normal and is not destroyed, called hyperthermia. The Protein denaturation begins at a temperature of approximately 60^{o}**C**, without any vaporization of the underlying tissue. The tissue whitens or blanches, similar to an egg white's albumin changes from clear to milky during cooking. It is useful in surgically removing diseased granulomatous tissue, and the biologically healthy portion can remain intact, if the tissue temperature can be controlled.

Coagulation refers to the irreversible damage to tissue, congealing liquid into a soft semi-solid mass. This process produces the desirable effect of hemostasis, by the contraction of the vessel wall. Soft tissue edges can be ‘‘welded’’ together with a uniform heating to 70 ^{0}C to 80 ^{0}C, the adherence of the layers is because of stickiness due to the collagen molecule’s helical unfolding and intertwining with adjacent segments. When the target tissue containing water is elevated to a temperature of 100^{o}C, vaporization of the water occurs, and the process is called ablation. And there is a physical change of state occurs, the solid and liquid components turn into vapor in the form of smoke or steam. Because of a high percentage of water present in the soft tissue, excision commences with this temperature. The apatite crystals and other minerals in dental hard tissue are not ablated by this temperature, but the water component is vaporized, and the resulting jet of steam expands and then explodes the surrounding matter into small particles. This micro-explosion of the apatite crystal is termed as ‘‘spallation.’’ This mixture of steam and solids is then suctioned away.

The tissue dehydrated and burned in the presence of air, if temperature continues to be raised to about 200 ^{0}C, and produce Carbon at the end, it absorbs all wavelengths.

The normal tissue ablation is prevented if the laser energy is applied continuously; the surface carbonized layer absorbs the incident beam and becomes a heat sink.

LASER–TISSUE INTERACTION:

Depending on the optical properties of the tissue, Laser light can have four kinds of different interactions. Dental structures have complex composition, and these four phenomena occur together in some degree relative to each other. Absorption of the laser energy by the intended tissue is the first and the most important interaction. The quantity

of energy absorbed by the tissue relies on the pigmentation, water content, laser wavelength and emission mode. Chormophores, which are tissue compounds, absorb certain wavelengths in preference (Fig 7).

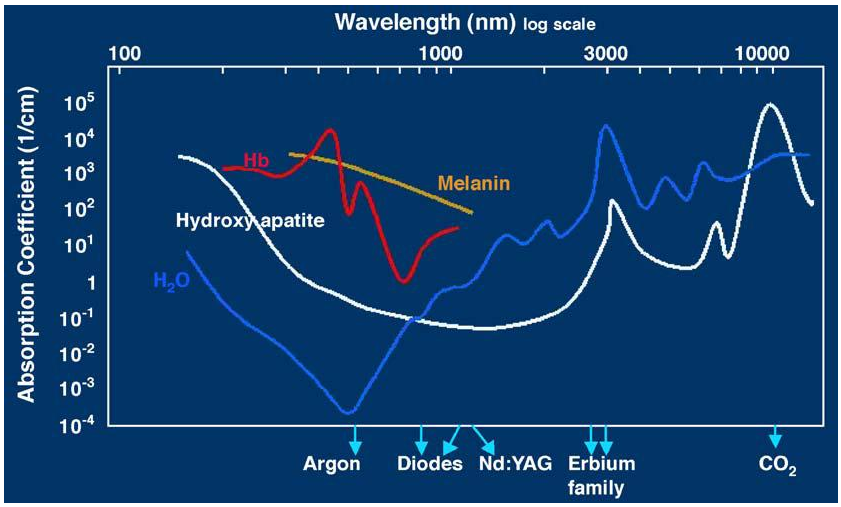


Figure 7: Approximate absorption curves of different dental compounds by various wavelengths of dental lasers.

Hemoglobin, that transports oxygen to tissue, reflects red wavelengths, imparting color to arterial blood. It is strongly absorbed by blue and green wavelengths. Venous blood, which contains less oxygen, absorbs more red light and appears darker. The pigment melanin, which imparts color to skin, is strongly absorbed by short wavelengths. Water, which is the universally present molecule, has different degrees of absorption by different wavelengths. Dental structures have different amounts of water content by weight. A ranking in the ascending order would show enamel (with 2% to 3%), dentin, bone, calculus, caries, and soft tissue (at about 70%). Hydroxyapatite is the chief

crystalline component of dental hard tissues and has a wide range of absorption depending on the wavelength.

Generally, the shorter wavelengths (from about 500–1000 nm) are instantly absorbed in pigmented tissue and blood elements. Hemoglobin highly attenuates Argon. Diode and Nd:YAG have great affinity for melanin and less interaction with hemoglobin. The longer wavelengths interact more with water and hydroxyapatite. The largest absorption peak for water is just below 3000 nm, which is at the Er:YAG wavelength. Erbium is also well absorbed by hydroxyapatite. Water absorbs CO2 at 10,600 nm and has the highest affinity for tooth structure.

The second effect is the inverse of absorption which is transmission of the laser energy directly through the tissue with no effect on the target tissue. This effect greatly depends on the wavelength of laser light. For eg, Water is relatively transparent to the shorter wavelengths like argon, diode, and Nd:YAG, but the tissue fluids readily absorb the erbium family and CO2 at the outer surface, so there is little energy transmitted to adjacent tissues. Fig. 8 explains this interaction by showing relative depth of penetration in water of various wavelengths.

The depth of the focused laser beam differs with the movement speed and the power density. In general, the erbium family acts with an absorption depth of approximately 0.01 mm mainly on the surface, whereas the 800-nm diodes are transmitted through the tissue to depths up to 100 mm, a factor of 10,000. As another example, the diode and Nd:YAG lasers are transmitted through the lens, iris, and cornea of the eye and are absorbed on the retina.

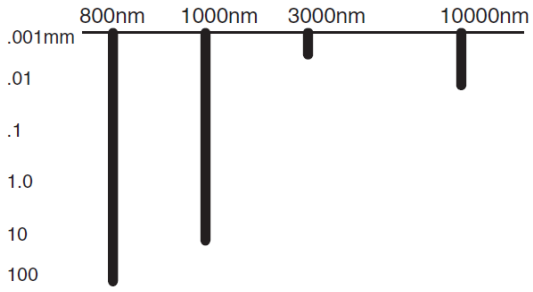


Figure 8: Relative depth of penetration in millimeters of different wavelengths in water. The vertical scale is logarithmic.

The third effect, which is reflection, is the beam redirecting itself off of the surface, having no effect on the target tissue. Reflected light is used by the caries-detecting laser device to measure the degree of sound tooth structure. The reflected light can either maintain its collimation in a narrow beam or become more diffuse. The laser beam diverges as the distance from the hand piece increases. However, the beam from some lasers can have adequate energy at distances over 3 m. This reflection can be dangerous as the energy is directed to an unintentional target, such as the eyes. This is a major safety concern for laser operation.

Scattering of the laser light is the fourth effect. It weakens the intended energy and possibly produces no useful biologic effects. It could cause heat transfer to the adjacent tissue of the surgical site, and unwanted damage could occur. However a beam deflected in different directions is useful in facilitating the curing of composite resin or in covering a broad area.

Absorption of the laser light by the target tissue is the primary and beneficial effect of laser energy. The aim of dental laser surgery is to optimize the photobiologic

effects of laser. Using the photothermal conversion of energy, incisions and excisions along with precision and hemostasis are main advantages of laser devices. Some photochemical effects of laser light can stimulate chemical reactions (eg, the curing of composite resin) and breaking of chemical bonds (eg, using photosensitized drugs exposed to laser light to destroy tumor cells, a process called photodynamic therapy). A special group of lasers emit in the ultraviolet ionizing range and are known as, the excimers. They have enough photon energy to directly break the chemical bond of an organic molecule without any thermal damage.

These are being investigated for hard tissue ablation procedures. When absorbing laser light, some biologic pigments can fluoresce, which can be used for caries detection within teeth. A laser can be used for biostimulation with powers well below the surgical threshold, producing more rapid wound healing, pain relief, increased collagen growth, and a general anti-inflammatory effect. The pulse of laser energy into a crystalline structure can produce an audible shock wave, which could explode or pulverize the tissue with mechanical energy. This is an example of the photoacoustic effect of laser light. [31]

BASIC DESIGN OF A DIODE LASER:

Main advantage of diode lasers is their size which is apparent to the naked eye. The development of laser emitting micro-structure diode cells reduced the bulk of laser systems to a great extent. The latest dental diode lasers have been designed with dimensions imitating a standard phone. Solid material active media (e.g. GaAlAs – Gallium Aluminum Arsenide) alone is used in diode lasers. Because of the crystalline nature of the active medium, the ends of the crystal can be selectively polished relative to internal refractive indices to produce totally and partially reflective surfaces thus serving

the same function as the optical resonators of larger laser systems. The discharge of current across the active medium releases photons from the active medium, finally resulting in the generation of laser light of a specific wavelength, which is determined by the active medium used (Fig 9).

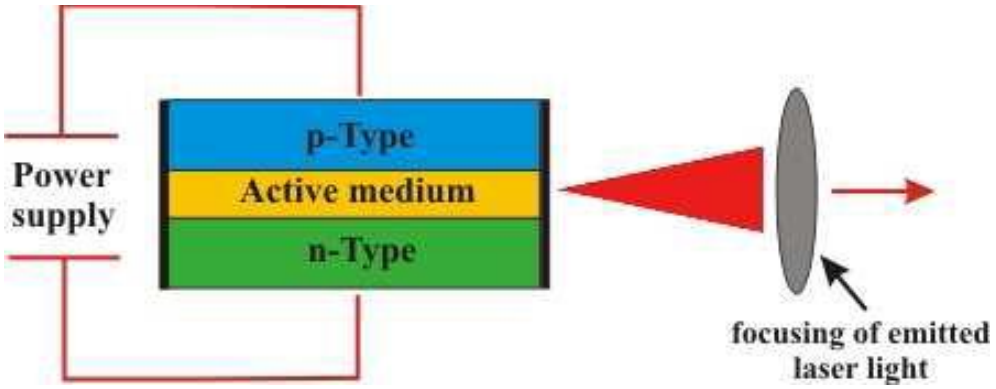


Figure 9: Simplified schematic outline of a typical diode laser

At present, each diode "chip" produces relatively low-energy output. Low power diode lasers operates in milliwatt range, are generally being advertised for low level laser therapy (LLLT). To achieve the power necessary for various dental procedures (e.g. soft tissue surgery), present dental diode lasers uses the banks of individual diode chips in parallel to obtain the appropriate power levels (several watts). Some dental diode lasers can also be set to lower power (milliwatt range) and can perform LLLT procedures also.[33]

TABLE 3: TYPE AND WAVELENGTH OF LASERS: [34]

Laser type		Wavelength	Color
Excimer lasers	Argon Fluoride (ArF)	193 nm	Ultraviolet
	Xenon Chloride (XeCl)	308 nm	Ultraviolet
Gas lasers	Argon	488 nm	Blue
		514 nm	Blue-green
	Helium Neon (HeNe)	637 nm	Red
	Carbon Dioxide (CO2)	10,600 nm	Infrared
Diode lasers	Indium Gallium Arsenide Phosphorus (InGaAsP).	655 nm	Red
	Gallium Aluminum Arsenide (GaAlAs)	670–830 nm	Red-infrared
	Gallium Arsenide (GaAs)	840 nm	Infrared
	Indium Gallium Arsenide (InGaAs)	980 nm	Infrared
Solid state lasers	Frequency-doubled Alexandrite	337 nm	Ultraviolet
	Potassium Titanyl Phosphate (KTP)	532 nm	Green
	Neodymium:YAG (Nd:YAG)	1,064 nm	Infrared
	Holmium:YAG (Ho:YAG)	2,100 nm	Infrared
	Erbium, chromium:YSGG (Er,Cr:YSGG)	2,780 nm	Infrared
	Erbium:YSGG (Er:YSGG)	2,790 nm	Infrared
	Erbium:YAG (Er:YAG)	2,940 nm	Infrared

ADVANTAGE:

1. Relatively bloodless surgical and post-surgical course
2. The ability to coagulate, vaporize, or cut tissue
3. Sterilization of wound tissue
4. Minimal swelling and scarring
5. No requirement of sutures
6. Little mechanical trauma
7. Reduced surgical time
8. Decreased post-surgical pain
9. High patient acceptance

DISADVANTAGE: [35]

1. The high financial cost of a laser apparatus
2. Each laser has different characteristics because of their different wavelengths.
3. Improper irradiation of teeth and periodontal pockets by lasers can damage the tooth and root surfaces as well as the attachment apparatus at the bottom of the pocket.
4. Possible damage to the underlying bone and dental pulp should also be considered.

Ozcelik O et al (2008) [36] reported a split-mouth controlled clinical trial to assess the effects of low-level laser therapy on healing of gingiva after gingivectomy and gingivoplasty in twenty patients with inflammatory gingival hyperplasias on their

symmetrical teeth and the results indicated that low-level laser therapy may enhance epithelization and improve wound healing after gingivectomy and gingivoplasty operations at third, seventh and 15th day ($p<0.001$ for each).

Lagdive S et al (2009) [3] studied a case series and described two simple and effective surgical depigmentation techniques – scalpel blade and solid-state semiconductor diode laser that typically uses a combination of Gallium (Ga), Arsenide (Ar), and other elements, such as Aluminum (Al) and Indium (In), – for gingival depigmentation and results revealed that the healing of laser wounds is slower than healing of scalpel wounds, as a sterile inflammatory reaction occurs after laser use.

Mani A et al (2009) [37] presented a case report with three different surgical depigmentation techniques: scalpel blade surgery, abrasion with diamond bur, and semiconductor diode laser. Better results were achieved with semiconductor diode laser than conventional scalpel blade and abrasion with bur.

Gupta G et al (2011) [38] reported simple and effective depigmentation technique using semiconductor diode laser surgery - for gingival depigmentation and results did not show any recurrence of pigments after 15-month follow-up. This has the advantages of easy handling, short treatment time, hemostasis, and decontamination and sterilization effects.

Simsek et al (2012) [39] compared the use of diode and Er:YAG lasers in treating of gingival depigmentation, local anesthesia requirements, postoperative pain/discomfort, depigmentation effectiveness, and total treatment duration and twenty patients (13 female, 7 male) were enrolled in the study and patients were randomly divided into 2 groups. Group 1 was treated with a gallium aluminum arsenide diode laser with a

continuous wavelength of 808 nm, and group 2 was treated with an Er:YAG laser with a continuous wavelength of 2,940 nm. Gingival depigmentation was performed by applying the laser at 1 W. The total length of treatment was significantly shorter with the diode laser than with the Er:YAG laser. No melanin recurrence was detected during any follow-up session. Diode and Er:YAG lasers administered at 1 W both result in satisfactory depigmentation.

Murthy M et al (2012) [5] presented a case series which described three simple and effective surgical depigmentation techniques-the scalpel technique, rotary abrasive technique, and a diode laser surgery - for gingival depigmentation and concluded that electrosurgery has its own limitations in that its repeated and prolonged use induces heat accumulation and undesired tissue destruction and scalpel surgery causes unpleasant bleeding during and after the procedure and blood vessels in the surrounding tissue up to a diameter of 0.5 mm are sealed by the laser; thus, the primary advantage is hemostasis and a relatively dry field.

Vishal Singh et al (2012) [40] compared the effectiveness and long-term stability of diode laser and tetrafluoroethane cryosurgery for depigmentation and results showed that at the 18-month follow-up, spotted repigmentation was found in one case in each group, although there was initial healing discomfort and mild pain with cryosurgery, all the patients were satisfied with the esthetic outcomes. They concluded that the depigmentation achieved using both the techniques were found equivalent and satisfactory.

Sanz-Moliner et al (2013) [41] presented a single-masked pilot clinical study to compare the tissue response and postoperative pain after the use of a diode laser (810 nm)

as an adjunct to modified Widman flap (MWF) surgery to that of MWF alone and thirteen patients with generalized severe chronic periodontitis completed the study. Control sites were randomly selected to receive an MWF and the contralateral test sites an MWF in conjunction with a diode laser. The study tooth/site was treated plus any additional teeth in the quadrant in which the site was located, if needed. The diode laser was used to de-epithelialize the inner part of the periodontal flap and photo-biostimulate the surgical area and concluded that the use of an 810-nm diode laser provided additional benefits to MWF surgery in terms of less edema and postoperative pain.

Giannelli et al (2014) [42] reported a randomized, split-mouth trial of two different photoablative dental lasers, erbium:yttrium-aluminum-garnet (Er:YAG) and diode for the treatment of gingival hyperpigmentation and results revealed that both diode and Er:YAG lasers gave excellent outcome in gingival hyperpigmentation, However, Er:YAG laser induced deeper gingival tissue injury than diode laser, as judged by bleeding at surgery, delayed healing, and histopathologic analysis. The use of diode laser showed additional advantages compared to Er:YAG in terms of less postoperative discomfort and pain and they suggested that diode laser can represent an effective and safe therapeutic option for gingival photoablation.

Materials and Methods

MATERIALS AND METHODS

SOURCE OF DATA:

Patients visiting the department of periodontics at the KSR institute of dental science & research, Tiruchengode, Namakkal dist, Tamil Nadu.

METHOD OF COLLECTION OF DATA:

The study protocol was analyzed and approved by the institutional ethical review board. Twenty systemically and periodontally healthy patients were included in the study. The patient complained excessive gingival melanin pigmentation in maxillary anterior region. The patients were selected based on inclusion and exclusion criteria, those who were willing to participate in the study. The need and outcome of the surgery was explained to the patients and a written consent was obtained.

INCLUSION CRITERIA:

a. Systemically and Periodontally healthy subjects.
b. Patients having bimaxillary melanin pigmentation in the maxillary anterior regions were evaluated as either moderate or heavy clinical pigmentation according to the criteria given by Dummett CO.
c. Age ranges from 18- 30 years.

EXCLUSION CRITERIA:

1. Smokers
2. Medically compromised patients
3. Pregnant and lactating women
4. Gingival pigmentation associated with various syndromes, lesions and conditions

STUDY DESIGN:

A total of 8 females and 12 males were enrolled in the study, and all the patients were in the age group 18- 30 years. Each patient underwent scaling, one week prior to periodontal surgery. The surgical sites extending from distal of the right canine to the midline and distal of the left canine to the midline in the maxilla were selected. In each patient, right side was treated with surgical scrapping technique and contra lateral left side was treated with diode laser technique in a single visit.

SURGICAL SCRAPPING TECHNIQUE:

Surgical technique was performed in complete aseptic precautions. Extra oral and intra oral mouth disinfection was done with 5% povidone - iodine solution. Local infiltration was done using 2% lignocaine hydrochloride with 1:80,000 adrenaline. Allotted region was demarcated with surgical scalpel blade No15 by two horizontal incisions that were placed at the apical and coronal extension of pigmentation following the gingival contours. Two vertical incisions were placed at the distal most line angles of the areas to be depigmented and continued apically to join the horizontal incision. The overlying epithelium and a portion of connective tissue were gently removed. Care was taken to avoid pitting of the gingival surface or removal of excess tissue. All the tissue remnants were removed as thoroughly as possible. Bleeding was controlled by pressure pack with sterile gauze. The depigmented area was covered with Coe-pack periodontal dressing for one week.

LASER TECHNIQUE:

The semiconductor diode laser unit (Zolar Technology & Mfg co. Inc, Canada; wavelength 810nm) was used (Figure 11). Before using the laser, parameters, such as

treatment option, energy output and pulse duration were determined based on manufacturers' instructions. Prime importance was given to laser safety. Protective eye classes were worn by patient, operator, and assistant. Highly reflective instruments were avoided. Topical anesthesia in the form of 2% lignocaine hydrochloride gel was applied to the surgical area. The energy output was set at 0.5 to 1.5 W and pulse mode was set as a continuous wave. Laser ablation started from the mucogingival junction toward the free gingival margin, including interdental papilla. The motion of ablation was performed as light brushing strokes and the tip was kept in motion all the time. Remnants of the ablated tissue were removed using sterile gauze dampened with saline solution. This procedure was repeated until the desired depth of tissue removal was achieved. The depigmented area was covered with Coe-pack periodontal dressing for one week.

POST SURGICAL CARE:

Post‑surgical instructions were given to the patient along with antibiotics (Amoxicillin 500 mg, three times daily for 5 days) and anti‑inflammatory analgesics (Ibuprofen and Paracetamol three times daily for 3 days). The patient was advised to use 0.2% chlorhexidine mouth wash 12th hourly for 1 week.

CLINICAL PARAMETERS TO BE ASSESSED:

The clinical parameters were assessed by Dummet oral pigmentation index (DOPI) for intensity of pigmentation and Hedin melanin index for extent of pigmentation at baseline and re-assessed at 1 month, 3 months and 6 months. Pain was evaluated by using the VAS at one day and 1 week post operative visit. Bleeding was assessed

immediately, 1 day, 1 week, 1 month, and 3 months after the procedure. Digital images of the pigmented gingiva were obtained base line and on post operatively 1 month, 3 months and 6 months.

DUMMETT ORAL PIGMENTATION INDEX (DOPI - 1964) FOR INTENSITY OF PIGMENTATION:

The criteria are as follows:

0 - No clinical pigmentation (Pink tissue).

1 - Mild clinical pigmentation (Mild, light brown tissue).

2 - Moderate clinical pigmentation (Medium brown or mixed pink or brown tissue).

3 - Heavy clinical pigmentation (Deep brown or blue/black tissue).

HEDIN MELANIN INDEX (1977) FOR EXTENT OF PIGMENTATION:

Hedin melanin index was scored as:

0- No pigmentation.

1- One or two solitary units of pigmentation in the papillary gingiva.

2- More than three units of pigmentation in the papillary gingiva without formation of a continuous ribbon

3- One or more short continuous ribbons of pigmentation

4- One continuous ribbon including the entire area between the canines

BLEEDING: (ISHI & KAWASHIMA-2002)

The assessment was performed on visual examination and based on the amount of bleeding encountered during the procedure and the case of carrying out the procedure. It was assessed as follows;

0 - No bleeding, complete haemostatic

1 - Isolated bleeding

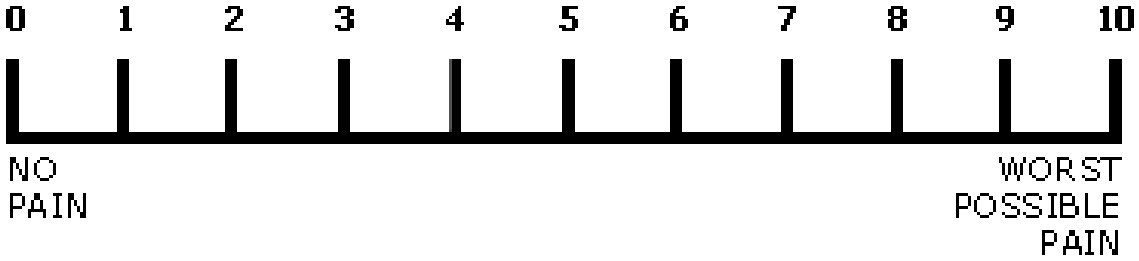
2 - Mild bleeding

3 - Moderate or severe bleeding

VISUAL ANALOG SCALE (VAS):

Pain was assessed on a 100 mm (10 cm) horizontal, continuous interval scale where the left end point was marked "No pain" and the right end point marked "Worst pain".

The patient was asked to mark the severity of the pain.



PHOTOGRAPHS:

Photographs were taken by Canon digital camera (Figure 12). As an attempt to standardize the images, each patients head was positioned and stabilized by a panoramic imaging unit according to the routine instructions used for orthopantomography. A digital camera was mounted on a tripod and the images were obtained at standard magnification and distance. [4x optical zoom, 20 cm]

ARMAMENTARIUM:

1. Kidney tray
2. Mouth mirror
3. William's graduated probe
4. Surgical gloves
5. Mask
6. Head cap
7. Tissue holding forceps
8. Surgical scissors
9. One rupee coin
10. Bard parker handle & blade no:15
11. Sterile gauze pieces
12. Local anaesthetics (2% lignocaine with 1:80,000 adrenaline)
13. Topical anaesthesia (lignocaine gel)
14. Semiconductor diode laser
15. Safety glasses

16. Disposable fiber optic tips
17. High suction
18. Saline
19. Coe-pak
20. Glass slab and spatula
21. Digital camera

ARMAMENTARIUM

Figure 10: Armamentarium for surgical stripping

Figure 11: Armamentarium for laser technique

Figure 12: Armamentarium for photographs

Canon digital camera [4x optical zoom, 20 cm]

Figure 13:

Preoperative view

Figure 14:

Demarcation of pigmented area

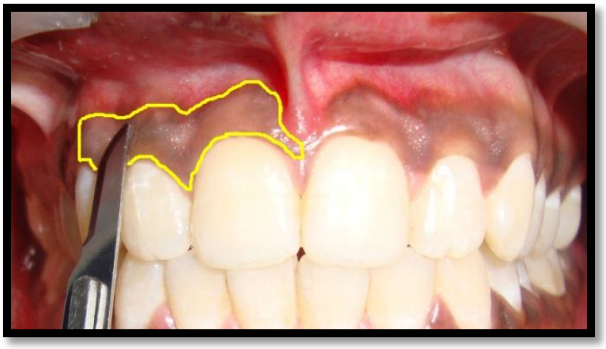


Figure 15:

Surgical stripping (Right Side& Yellow colour area)

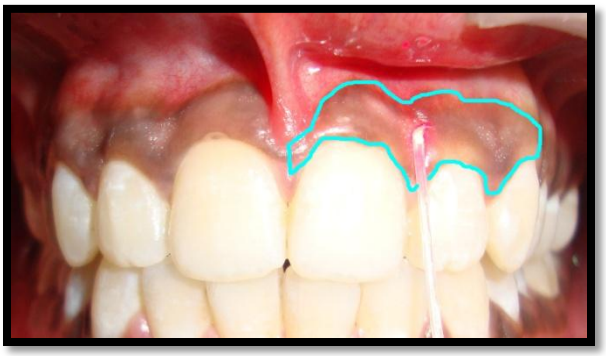


Figure 16:

Laser technique (Left Side & Blue colour area)

Figure 17:

Immediate postoperative view

Figure 18:

Operated area covered with Coe-Pak

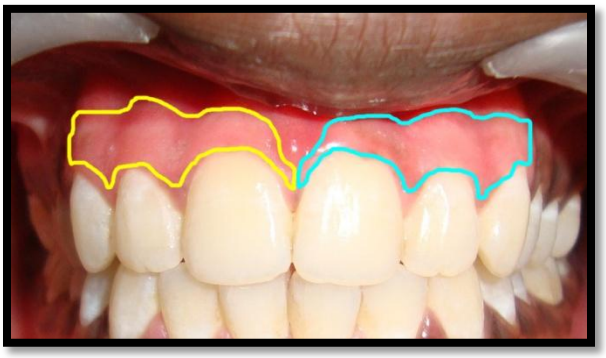


Figure 19:

1 Month post operative view

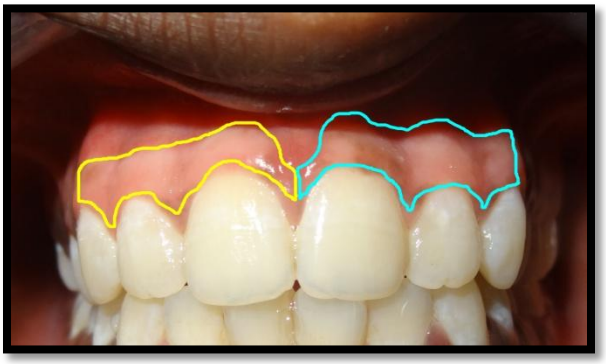


Figure 20:

3 Months post operative view

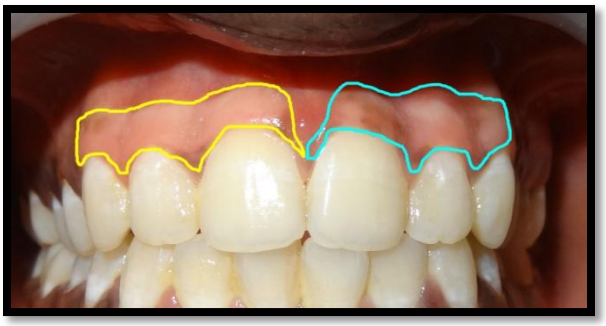


Figure 21:

6 Months post operative view

Statistical Analysis

STATISTICAL ANALYSIS

FRIEDMAN TEST:

A non-parametric test (distribution-free) used to compare observations repeated on the same subjects. This is also called a non-parametric randomized black analysis of variance.

MANN–WHITNEY *U* TEST:

The Mann–Whitney *U* test is a nonparametric test of the null hypothesis that two populations are the same against an alternative hypothesis, especially that a particular population tends to have larger values than the other.

P VALUE:

The P value or calculated probability is the estimated probability of rejecting the null hypothesis of a study question when that hypothesis is true. Differences between the two populations were considered significant when $p < 0.05$.

Results

RESULTS

A total of 8 females and 12 males were enrolled in the study, and all the patients were in the age group 18 to 30years. The surgical sites extending from distal of the right canine to the midline and distal of the left canine to the midline in the maxilla were selected. In each patient, right side was treated with surgical scrapping and left side was treated with diode laser technique in a single visit.

Table no.4 shows the age and sex distribution of the gingival hyperpigmentation patients. All the 20 patients belong to the age group 17 to 30 years. In that 50% of them have been in the age group of 17 to 20 years, 60% of them being males.

Table no.5 shows the intensity of pigmentation in patients treated with surgical scrapping method at baseline, at the end of 1^{st}, 3^{rd}, and 6^{th} month after the treatment. Before intervention with surgical scrapping, the intensity of the pigmentation was severe. After the treatment at the end of the 1^{st} month, the pigmentation status has been quite normal for all the 20 patients. However, at the end of 3^{rd} month after the treatment with scrapping, 20% of the patients had a mild intensity of pigmentation. Similarly at the end of 6^{th} month, 10 % and 15% of the patients had a moderate and mild intensity of pigmentation at the site of the treatment respectively and 75% of the patients had no hyperpigmentation. The above changes has been statistically assessed and founds to be significant at $P<0.001$ level. The results indicate that scrapping method is effective in reducing the intensity of the pigmentation in patients with gingival hyperpigmentation.

Table no.6 shows the extent of pigmentation in the hyperpigmentation patients treated with surgical scrapping at baseline, 1st month, 3rd month and at 6th month. At baseline (before intervention) all 20 patients show one full continuous pigmentation on the entire area between the canines. After the scrapping intervention, pigmentation has become normal structure. However, after the 3rd and 6th month of treatment, for few subjects one or two units of pigmentation have been appeared in the papillary gingiva. Friedman's test has been applied to find out whether surgical scrapping treatment is effective in controlling the extent of pigmentation. The significant p-value of the test reveals that surgical scrapping treatment is effective in controlling the extent of pigmentation of the hyperpigmentation patients.

Table no.7 shows the bleeding status of the hyperpigmentation patients during the surgical scrapping treatment at the end of 1st week, 1st month and 3rd month. Immediately after the treatment, 20% and 70% of them show moderate and mild level of bleeding respectively. At the end of 1st week, no bleeding appeared at the treatment site and it comes to normal and continues thereafter.

Table no.8 shows the pain level of the hyperpigmentation patients treated with surgical scrapping at the end of 1st day and 1st week after the treatment. 10% of patients experience moderate level of pain on the 1st day. At the end of 1st week after the surgery, no pain has been experienced by the patients.

Table no.9 shows the intensity of the pigmentation of the hyperpigmentation patients treated with diode laser at baseline, 1st month, 3rd month and 6th month. Before intervention, all the 20 patients have severe intensity of pigmentation. Friedmann's statistical test has been

applied to assess the effectiveness of the laser treatment. The significant p-value infers that the laser treatment is effective in reducing the intensity of the pigmentation.

Table no.10 shows the extent of pigmentation of the hyperpigmentation patients treated with diode laser at baseline, 1st month, 3rd month and 6th month after the treatment. The significant p-value of the Friedmann's test infers that the laser treatment has been effective in controlling the extent of pigmentation.

Table no.11 shows the bleeding status of the hyperpigmentation patients treated with diode laser immediately and at 1st week, 1st month and 3rd month after the treatment. Immediately after the laser treatment, 10% of the patients had mild bleeding at the sites where the treatment has been provided.

Table no.12 shows the pain level of the hyperpigmentation patients treated with diode laser at the end of 1st day and 1st week after the treatment. Majority of the patients experienced no pain immediately after the treatment with laser.

Table no.13 shows the comparison between two treatments with respect to the intensity of pigmentation at the end of the 6th month. Mann-Whitney test has been applied to find out if there is any statistical difference between the two treatments. The non-significant p-value infers that the intensity level at the end of sixth months after the treatment has been similar for the two treatments. **Graph no.1** shows the intensity of pigmentation of the hyperpigmentation patients at the sixth month after the respective treatments.

Table no.14 shows the extent of pigmentation at the end of the sixth month after respective treatments of surgical scrapping and diode laser. The non-significant p-value of the Mann-Whitney test infers that the extent of pigmentation at the end of sixth month has been

similar for the two treatments. **Graph no.2** shows the extent of pigmentation of the hyperpigmentation patients at the end of the sixth month after respective treatments of surgical scrapping and diode laser.

Table no.15 shows the bleeding status of the hyperpigmentation patients immediately after the respective treatments. In the surgical scrapping method, 20% of the patients experienced a moderate level of bleeding immediately after the treatment. However, in the laser treatment, no significant bleeding was observed. The significant p-value of the Mann-Whitney test reveals that the two treatments are statistically different with respect to the bleeding status of the patients treated with the respective treatments. **Graph no.3** shows the bleeding status immediately after the corresponding treatments for hyperpigmentation.

Table no.16 shows the mean and standard deviation of the pain level at the end of 1st day between the surgical scrapping and diode laser treatment. The average level of pain has been 1.00 and 0.20 respectively for the patients treated with surgical scrapping and diode laser. Independent t-test has been applied to compare the two mean values. The significant p-value confirms that patients whenever treated with surgical scrapping experienced higher level of pain compared with diode laser method. **Graph no.4** shows the mean and standard deviation of pain level on day 1 after the respective treatments.

Table no.4: Age and sex distribution of the gingival hyperpigmentation patients

Variable	No.	%
Age		
17-20 years	10	50.0
21-30 years	10	50.0
Sex		
Male	12	60.0
Female	8	40.0

Table no.5: Intensity of pigmentation in hyperpigmentation patients treated with surgical scrapping at baseline, 1st month, 3rd month and 6th month after the treatment.

Intensity of Pigmentation	Baseline		1st Month		3rd Month		6th Month	
	No.	%	No.	%	No.	%	No.	%
Nil			20	100	16	80	15	75.0
Mild					4	20	3	15.0
Moderate							2	10.0
Heavy	20	100						

Friedmann's test value=54.15 P-value <0.001

Table no.6: Extent of pigmentation in hyperpigmentation patients treated with surgical scrapping at baseline, 1st month, 3rd month and at 6th month after the treatment.

Extent of Pigmentation	Baseline		1st Month		3rd Month		6th Month	
	No.	%	No.	%	No.	%	No.	%
No pigmentation			20	100	16	80	15	75.0
One or two solitary units in the papillary gingiva					4	20	4	20.0
Three or more units in the papillary gingiva without continuous ribbon							1	10.0
One or more short continuous ribbons of pigmentation								
One continuous ribbon including the entire area between the canines	20	100						

Friedmann's test value=54.4 P-value<0.001

Table no.7: Bleeding status of the hyperpigmentation patients treated with surgical scrapping at immediately, 1st week, 1st month and 3rd month after the treatment

Bleeding	Immediate		1st Week		1st Month		3rd Month	
	No.	%	No.	%	No.	%	No.	%
No bleeding	2	10.0	20	100	20	100	20	100
Isolated bleeding	0	--						
Mild bleeding	14	70.0						
Moderate bleeding	4	20.0						

Table no.8: Pain level of the hyperpigmentation patients treated with surgical scrapping at 1st day and 1st week.

Pain Level	Day 1		1st Week	
	No.	%	No.	%
No	11	55.0	20	100
Slight	7	35.0		
Moderate	2	10.0		
Severe				

Table no.9: Intensity of pigmentation in hyperpigmentation patients treated with diode laser at baseline, 1st month, 3rd month and 6th month after the treatment.

Intensity of Pigmentation	Baseline		1st Month		3rd Month		6th Month	
	No.	%	No.	%	No.	%	No.	%
Nil			20	100	16	80	14	70.0
Mild					4	20	2	10.0
Moderate							4	20.0
Heavy	20	100						

Friedmann's test value-53.32 P-value <0.001

Table no.10: Extent of pigmentation in the hyperpigmentation patients treated with diode laser at baseline, 1st month, 3rd month and 6th month after the treatment.

Extent of Pigmentation	Baseline		1st Month		3rd Month		6th Month	
	No.	%	No.	%	No.	%	No.	%
No pigmentation			20	100	16	80	14	70.0
One or two solitary units in the Papillary gingiva					4	20	3	15.0
Three or more units in the papillary gingiva without continuous ribbon							2	10.0
One or more short continuous ribbons of pigmentation							1	5.0
One continuous ribbon including the entire area between the canines	20	100						

Friedmann's test value=53.3 P-value<0.001

Table no.11: Bleeding status of the hyperpigmentation patients treated with diode laser at immediately, 1st week, 1st month and 3rd month after the treatment

Bleeding	Immediately		1st Week		1st Month		3rd Month	
	No.	%	No.	%	No.	%	No.	%
No bleeding	8	40.0	20	100	20	100	20	100
Isolated bleeding	10	50.0						
Mild bleeding	2	10.0						
Moderate bleeding								

Table no.12: Pain level of the hyperpigmentation patients treated with diode laser at 1st day and 1st week.

Pain Level	Day 1		1st Week	
	No.	%	No.	%
No	16	80.0	20	100
Slight	4	20.0		
Moderate				
Severe				

Table no.13: Comparison of intensity of pigmentation at the 6th month between the two treatments

Intensity of pigmentation	Surgical Scrapping		Diode laser	
	No.	%	No.	%
Nil	15	75.0	14	70.0
Mild	3	15.0	2	10.0
Moderate	2	10.0	4	20.0
Heavy				

Mann-Whitney test value=186.0 P-value=0.718

Table no.14: Comparison of extent of pigmentation at 6th month between the treatments

Extent of pigmentation	Surgical Scrapping		Diode laser	
	No.	%	No.	%
No pigmentation	15	75.0	14	70.0
One or two solitary units in the papillary gingiva	4	20.0	3	15.0
Three or more units in the papillary gingiva without continuous ribbon	1	10.0	2	10.0
One or more short continuous ribbons of pigmentation			1	5.0
One continuous ribbon including the entire area between the canines				

Mann-Whitney test value=185.0 P-value=0.698

Table no.15: Comparison of bleeding status immediately after the treatment for the two treatments

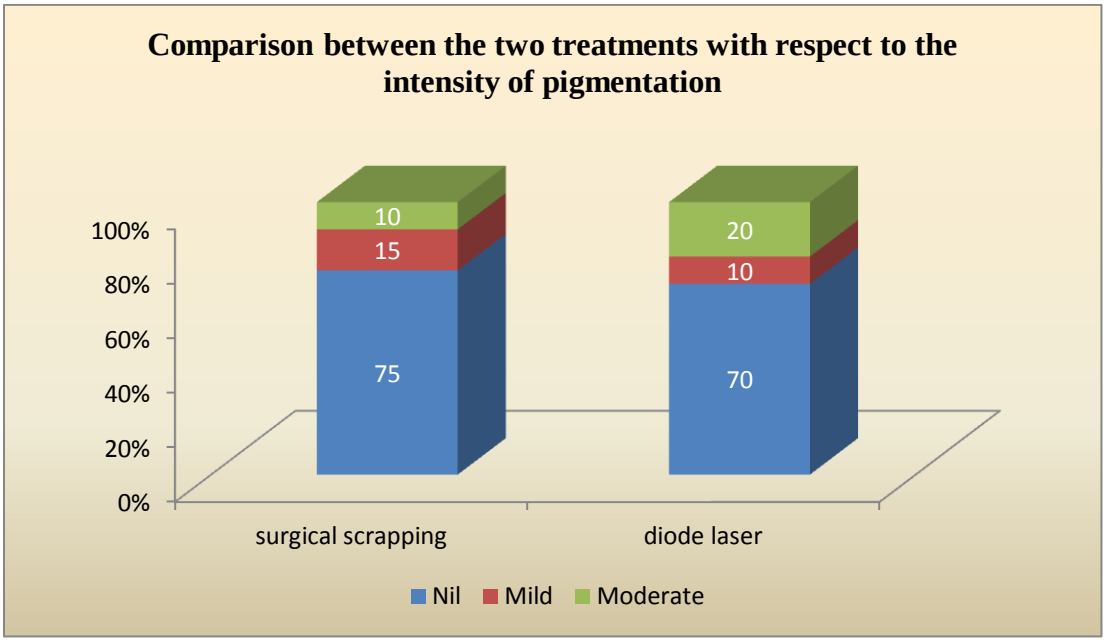
Bleeding Status	Surgical Scrapping		Diode laser	
	No.	%	No.	%
No bleeding	2	10.0	8	40.0
Isolated bleeding	0	--	10	50.0
Mild bleeding	14	70.0	2	10.0
Moderate bleeding	4	20.0	0	

Mann-Whitney test value=46.0 P-value<0.001

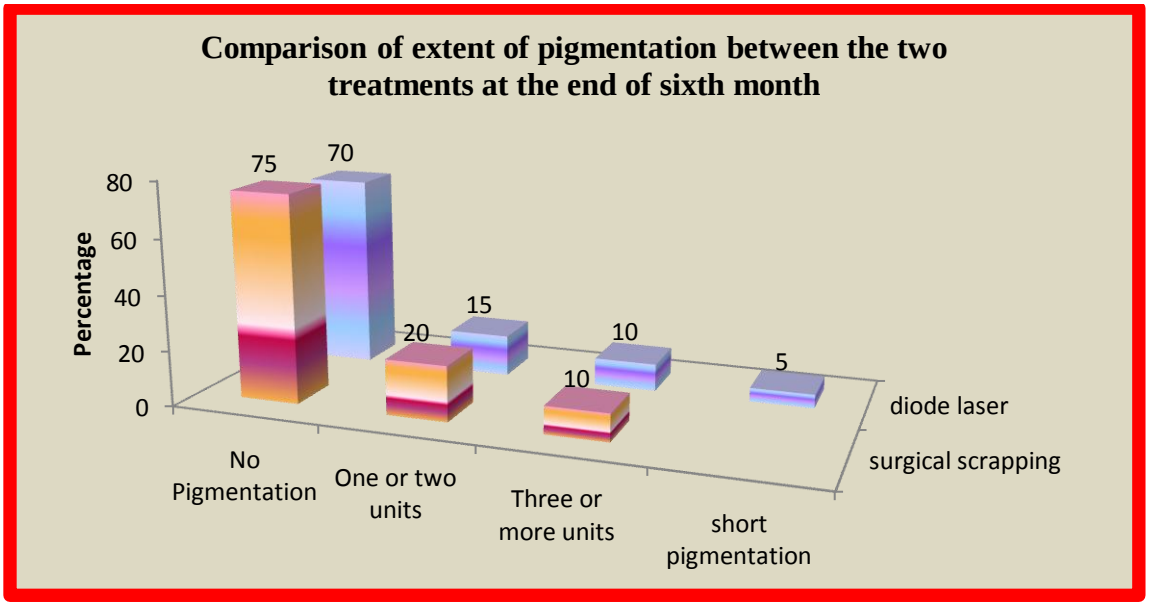
Table 16: Comparison of pain level at the end of 1st day between the two treatments

Treatment	Minimum	Maximum	Mean	Standard deviation	Independent t-value	p-value
Surgical Scrapping	0	4	1.00	1.414	2.430	0.02
Diode laser	0	1	0.20	0.410		

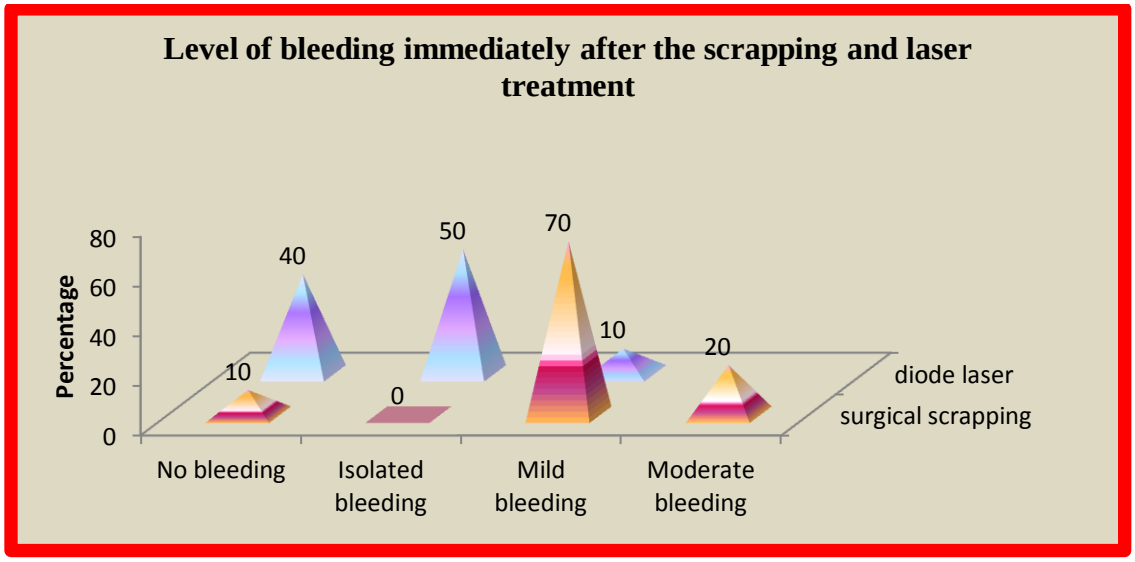
Graph no.1: Comparison of intensity of pigmentation at the end of the sixth month between the surgical scrapping and diode laser treatments



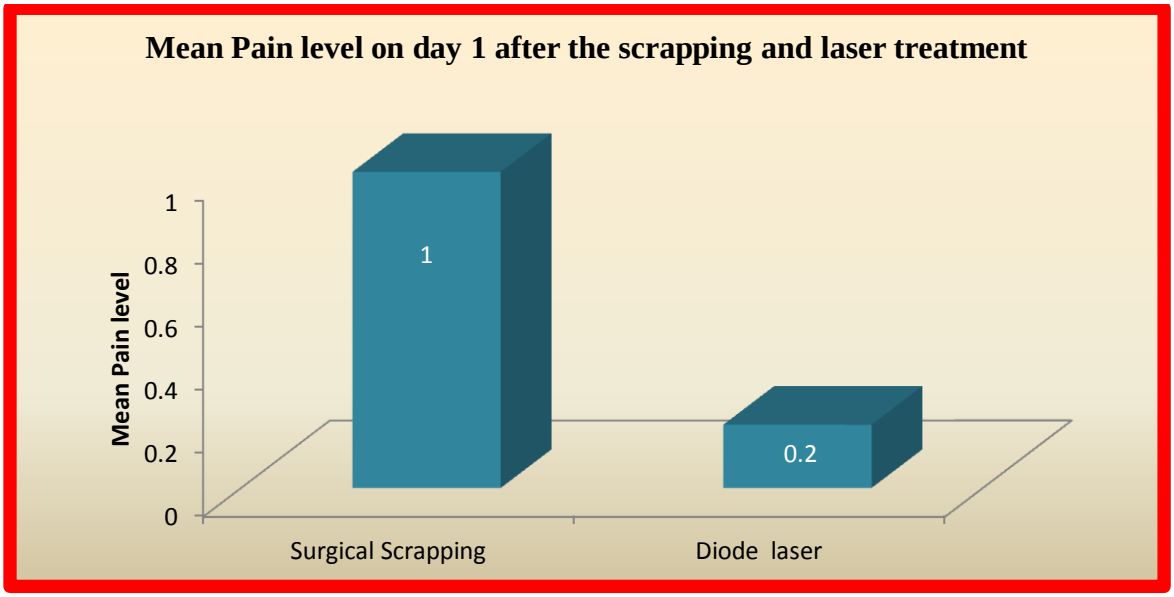
Graph no.2: Extent of pigmentation between the two treatments at the end of sixth month after the respective treatments



Graph no.3: Bleeding status immediately after the treatments between surgical scrapping and laser treatment.



Graph no.4: Mean and Standard deviation of pain level on day 1 after respective treatments.



Discussion

DISCUSSION

Gingival pigmentation is physiologic and does not present any medical complications. It causes esthetic concerns and demand is made for the removal of broad black zone of pigmentation from gums for the same reason. [1]

Gingival depigmentation is a periodontal plastic surgical procedure where different techniques are used to remove or reduce the gingival hyperpigmentation. De-epithelization (Scalpel, and Gingival abrasion technique using diamond bur), Gingivectomy, Gingivectomy with free gingival autografting, Acellular dermal matrix allograft, Electrosurgery, Cryosurgery, Chemical agents, and Lasers are some of the techniques used. [5]

Surgical removal of the pigmentation using scalpel technique is one of the earlier techniques and is still considered as gold standard. In recent years, the use of laser photoablation has been recognized as one of the most effective, pleasant, and reliable techniques for this purpose. The commonly used lasers for gingival deepithelialization include semiconductor diode, Er:YAG, Nd:YAG, and CO2 laser. [1]

In our study, all the 20 patients have been in the age group of 17 years to 30 years. In that 50% of them have been in the age group of 17 years to 20 years. 60% of the patients have been males.

In the present study, 20% of patients under the surgical scrapping method experienced a moderate level of bleeding immediately after the treatment. However, in the laser treatment, no significant bleeding was observed. The significant p-value (<0.001) of the Mann-Whitney test reveals that the two treatments are statistically

different with respect to the bleeding status of the patients treated with the respective treatments.

Our study results are similar to the previous studies of **Lagdive et al (2009) [3], Mani et al (2009) [37], Kathariya et al (2011) [4], Murthy et al (2012) [5], Hedge et al (2013) (p value < 0.001) [25]** and **Giannelli et al (2014) (p value < 0.05) [42].**

The diode laser treatment showed lesser bleeding because of the photocoagulation of the blood vessels, due to the absorption of light in its blood column, which heats hemoglobin to a temperature high enough to produce thrombus formation and collagen shrinkage in the wall of the blood vessel and its surrounding connective tissues. Light absorption by hemoglobin varies according to the wavelength and oxygen saturation. Ideally, photon penetration depth for a laser wavelength used in vessel closure should be roughly equal to the vessel diameter so that there is effective bulk heating of the blood column without superficial damage of perforation of the vessel wall at the treatment site.[43] The laser seals the blood vessels in the surrounding tissue up to a diameter of 0.5 mm thus; the primary advantage is hemostasis and a relatively dry field. [3]

The Visual Analog Scale (VAS) was used for evaluating the pain scores. In our study VAS showed that, the average level of pain has been 1.00 and 0.20 respectively for the patients treated with surgical scrapping and diode laser method at the end of 1st day. Independent t-test has been applied to compare the two mean values. The significant p-value confirms that patients whenever treated with surgical scrapping experienced higher level of pain compared with diode laser method.

Our results are similar to the previous studies done by **Tal et al (2003)** [44]**, Esen et al (2004) (p value < 0.05)** [45]**, Rosa et al (2007)** [46]**, Hedge et al (2013) (p value < 0.001)** [25] and **Giannelli et al (2014) (p value < 0.05)** [42] **.**

Pain reduction after laser application may be attributed to the protein coagulum formed on the wound surface which acts as a biologic dressing or to the laser's ability to seal the ends of sensory nerves. [39] In contrast to this, the surgical scrapping procedure, results in a raw, bleeding surface, with exposed nerve endings which could lead to greater postoperative pain, depending on the depth of penetration into the connective tissue and the patient's pain threshold. [25]

The Dummet Oral Pigmentation Index (DOPI) was used to check the intensity of pigmentation. The Mann-Whitney test has been applied to find out if there is any statistical difference between the two treatments with respect to the intensity of pigmentation at the end of 6^{th} month. The non-significant p-value (0.718) infers that the intensity level at the end of sixth month after the treatment has been similar for the two treatments.

The Hedin Index was also used to check the degree and extent of pigmentation. The non-significant p-value (0.698) of the Mann-Whitney test infers that the extent status of the hyper pigmentation patients at the end of sixth month has been similar for the two treatments with respect to the extent of pigmentation at the end of 6^{th} month.

In the present study gingival wound healing showed no significant differences in both treatments. However diode laser yielded a complete removal of the gingival surface epithelium without causing stromal damage. Microvessel dilation and the epithelial photoablation was accompanied by microvessel narrowing, possibly related to direct

vasomotor effects and/or deactivation of local proinflammatory mediators by the diode laser light. These features attribute to heat-induced coagulation of the targeted tissues induced by this laser type. [42]

The diode laser induces the expression of cytokines and growth factors which are responsible for many phases of wound healing. There is a report that laser increased both protein and mRNA levels of IL-1α and IL-8 responsible for the initial inflammatory phase of wound healing in keratinocytes, can upregulate bFGF, HGF and SCF, which are the cytokines responsible for fibroblast proliferation and migration, can increase growth factors such as VEGF and TGF-β responsible for neovascularization and collagen synthesis respectively. There are also reports that diode laser can induce fibroblasts to undergo the transformation into myofibloblasts, a cell type that expresses smooth muscle α-actin and desmin and has the phenotype of contractile cells that hasten wound contraction. [47]

In the present study, repigmentation was observed in 4 patients out of 20 patients those were having heavy clinical pigmentation according to the criteria given by Dummett CO.

Our results are in contrast to the previous studies done by,

Atsawasuwan et al (2000) [48], Tal et al (2003) [44], Hasumi et al (2006) [49] and Giannelli et al (2014). [42]

Our study results are similar to the following studies,

Esen et al (2004) [45], Rossa A et al (2007) [46], Kaur et al (2010) [1] and **Hedge et al (2013).** [25]

It has been suggested that recurrence of gingival hyperpigmentation may initiate from the epithelial resettlement of residual melanocytes migrated from the gingival areas that are less easily accessible to surgical maneuvers, such as the gingival margins and interdental papilla and also adequate tissue removal may not be possible at these areas due to close proximity of the adjacent teeth, which may be damaged by the laser beam. These limitations may result in incomplete vaporization of the pigment in such delicate areas, which tends to promote repigmentation. [42, 45]

Summary and Conclusion

SUMMARY AND CONCLUSION

Growing cosmetic demand necessitates removal of gingival melanin hyperpigmentation for esthetics. In recent years, the use of laser photoablation has been recognized as one of the most effective, pleasant, and reliable techniques for this purpose. The present study was undertaken to compare the clinical efficacy and patient comfort of surgical scrapping and diode laser technique for gingival depigmentation. The following conclusions were derived following analysis of the data obtained:

1. Intragroup comparisons of Dummet Oral Pigmentation Index showed statistically significant results in achieving depigmentation. The non-significant p-value infers that the intensity level at the end of sixth month after the treatment has been similar for the two treatments.
2. Intragroup comparisons of Hedin Melanin Index showed statistically significant results in achieving depigmentation. The non-significant p-value infers that the extent status of the hyper pigmentation patients at the end of sixth month has been similar for the two treatments.
3. The amount of bleeding was significantly higher in the surgical scrapping sites as compared to diode laser sites. This led to improved visibility, easy handling and short treatment time when performed with diode laser.
4. Postoperative pain was significantly higher in the surgical scrapping sites as compared to diode laser sites at 1 day postoperative. However at 1 week post surgery the difference in pain was insignificant.

Based on the data obtained from the study, it can be concluded that diode laser can be used as an alternative technique for gingival depigmentation. However surgical scrapping continues to remain as a cost effective and gold standard procedure to achieve gingival depigmentation. Nevertheless it is proposed that further long term studies has to be undertaken with bigger sample size for monitoring along with histopathological assessment to understand the process of repigmentation.

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Annexure

ANNEXURE 1

INFORMATION SHEET

We are conducting a study on A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL.

The identity of the patients participating in the research will be kept confidential throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in the study is voluntary. You are free to decide whether to participate in the study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Name of the patient Signature / Thumb impression

Name of the investigator Signature

Date

ANNEXURE 2

INFORMED CONSENT FORM

A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL

Name: Age/Sex: O.P.no:

Address:

I, age years exercising my free power of choice, hereby give my consent to be included as a participant in the study "A comparative evaluation of clinical efficacy and patient comfort in surgical scrapping and diode laser technique for gingival depigmentation: A clinical trial". I agree to the following:

I have been informed to my satisfaction on about the purpose of the study and study procedures including investigations to monitor and safeguard my body function.

I agree to co-operate fully and to inform my doctor immediately if I suffer any unusual symptom.

I have informed the doctor about all medications I have taken in the recent past and those I am currently taking.

I hereby give permission to use my medical records for research purpose. I am told that the investigating doctor and institution will keep my identity confidential.

Name of the patient Signature / Thumb impression

Name of the investigator Signature

Date

ஆராய்ச்சி ஒப்புதல் கடிதம்

லேசர் சிகிச்சை (Diode Laser) மற்றும் அறுவை சிகிச்சை (Surgical Scrapping) யால் கருப்பு நிற ஈறை சிகப்பு நிற ஈறாக மாற்றி, அதனுடைய மருத்துவ திறனையும் (Clinical Efficacy) மற்றும் நோயாளியின் வசதியையும் (Patient Comfort) ஒப்பிடுதல். இது ஒரு மருத்துவ சோதனை

பெயர்	:	தேதி	:
வயது	:	புற நோயாளி எண்	:
பாலினம்	:	ஆராய்ச்சி சேர்க்கை எண்	:

என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆராய்ச்சியில் சேர்த்துக் கொள்ள ஒப்புதல் அளிக்கிறேன்.

கீழ்காணப்படும் நிபந்தனைகளுக்கு நான் ஒப்புதல் அளிக்கிறேன்.

★ இந்த ஆராய்ச்சியின் நோக்கமும், செயல்முறைகளும் எனக்கு திருப்தியளிக்கும் வகையில் அறிவுறுத்தப்பட்டது.

★ நான் ஏற்கனவே உட்கொண்ட மற்றும் உட்கொள்கிற மருந்துகளைப் பற்றிய விபரங்கள் ஆராய்ச்சியாளரிடம் தெரிவித்துள்ளேன்.

★ என் உடல்நலம் பாதிக்கப்பட்டாலோ அல்லது எதிர்பாராத வழக்கத்திற்கு மாறான நோய்க்குறி தென்பட்டாலோ அதனை உடனடியாக மருத்துவரிடம் தெரிவிக்க சம்மதிக்கிறேன்.

★ என் மருத்துவ குறிப்பேடுகளை இந்த ஆராய்ச்சியில் பயன்படுத்திக் கொள்ள சம்மதிக்கிறேன். இந்த ஆராய்ச்சி மையமும், ஆராய்ச்சியாளரும் என்னுடைய விவரங்கள் அனைத்தையும் இரகசியமாக வைப்பதாக அறிகிறேன்.

.....	.....	.....
நோயாளியின் பெயர்	கையொப்பம்	தேதி
.....	.....	.....
ஆராய்ச்சியாளரின் பெயர்	கையொப்பம்	தேதி

ANNEXURE 3

A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL

PROFORMA

Name: Date:

Age /sex: Op number:

S.NO:

Occupation:

Address and contact no:

Chief complaints:

Medical history:

Dental history:

DUMMETT ORAL PIGMENTATION INDEX (DOPI) : 1964

(FOR INTENSITY OF PIGMENTATION)

AT BASELINE:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 1 MONTH:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 3 MONTHS:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 6 MONTHS:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

HEDIN MELANIN INDEX: 1977

(FOR EXTENT OF PIGMENTED AREA)

AT BASELINE:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 1 MONTH:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 3 MONTHS:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

AFTER 6 MONTHS:

(SCALPEL) (DIODE LASER)

13	12	11	21	22	23

THE VISUAL ANALOG SCALE (VAS)

AFTER 1 DAY:

SCALPEL:

DIODE LASER:

AFTER 1 WEEK:

SCALPEL:

DIODE LASER:

BLEEDING

(Ishii and Kawashima et al 2002)

IMMEDIATE:

(SCALPEL) (DIODE LASER)

A: none; B: slight; C: moderate; D: severe A: none; B: slight; C: moderate; D: severe

24 HOURS:

(SCALPEL) (DIODE LASER)

A: none; B: slight; C: moderate; D: severe A: none; B: slight; C: moderate; D: severe

1 WEEK :

(SCALPEL) (DIODE LASER)

A: none; B: slight; C: moderate; D: severe A: none; B: slight; C: moderate; D: severe

1 MONTH :

(SCALPEL) (DIODE LASER)

A: none; B: slight; C: moderate; D: severe A: none; B: slight; C: moderate; D: severe

3 MONTHS:

(SCALPEL) (DIODE LASER)

A: none; B: slight; C: moderate; D: severe A: none; B: slight; C: moderate; D: severe

INSTITUTIONAL ETHICAL COMMITTEE

KSR INSTITUTE OF DENTAL SCIENCE & RESEARCH

KSR Kalvi Nagar, Tiruchengode-637 215, Tamilnadu.
Phone : 04288-274981, Fax : 04288-274761,
email : ksrdentalcollege@yahoo.com

Ref.: 034 /KSRIDSR/EC/2013 **Date : 01.02.2013**

To

Dr.M.Ragul,
Postgraduate Student,
Dept. of Periodontics,
KSR Institute of Dental Science & Research,

*****

Your dissertational study titled "A COMPARATIVE EVALUATION OF CLINICAL EFFICACY AND PATIENT COMFORT IN SURGICAL SCRAPPING AND DIODE LASER TECHNIQUE FOR GINGIVAL DEPIGMENTATION: A CLINICAL TRIAL" presented before the ethical committee on 29th Jan.2013 has been discussed by the committee members and has been approved.

You are requested to adhere to the ICMR guidelines on Biomedical Research and follow good clinical practice. You are requested to inform the progress of work from time to time and submit a final report on the completion of study.

Signature of Secretary
(Dr.G.S.Kumar)